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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,723	08/10/2005	Nicolaas Duneas	2226-045890	1009
28289 THE WEBB LA	7590 04/28/200 AW FIRM, P.C.	EXAMINER		
700 KOPPERS BUILDING 436 SEVENTH AVENUE			KEMMERER, ELIZABETH	
PITTSBURGH, PA 15219			ART UNIT	PAPER NUMBER
			1646	
			MAIL DATE	DELIVERY MODE
			04/28/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)			
	10/518,723	DUNEAS, NICOLAAS			
Office Action Summary	Examiner	Art Unit			
	Elizabeth C. Kemmerer, Ph.D.	1646			
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the c	orrespondence address			
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period w.  - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tim vill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	lely filed the mailing date of this communication. (35 U.S.C. § 133).			
Status					
Responsive to communication(s) filed on <u>21 Fee</u> This action is <b>FINAL</b> . 2b) ☑ This     Since this application is in condition for allowar closed in accordance with the practice under E	action is non-final. nce except for formal matters, pro				
Disposition of Claims					
4) ☐ Claim(s) 36-50 is/are pending in the application 4a) Of the above claim(s) 37-50 is/are withdraw 5) ☐ Claim(s) is/are allowed. 6) ☐ Claim(s) 36 is/are rejected. 7) ☐ Claim(s) is/are objected to. 8) ☐ Claim(s) are subject to restriction and/or Application Papers 9) ☐ The specification is objected to by the Examine 10) ☐ The drawing(s) filed on 20 December 2004 is/ar	rn from consideration. relection requirement. r. re: a)⊠ accepted or b)⊡ object	•			
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).					
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.					
Priority under 35 U.S.C. § 119					
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>					
Attachment(s)  1) Notice of References Cited (PTO-892)  2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 2/23/06, 8/27/07.	4)  Interview Summary Paper No(s)/Mail Da 5)  Notice of Informal P 6)  Other:	ite			

**DETAILED ACTION** 

Election/Restrictions

Applicant's election without traverse of Group I (claim 36) in the reply filed on 21

February 2008 is acknowledged.

Claims 37-50 are withdrawn from further consideration pursuant to 37 CFR

1.142(b) as being drawn to a nonelected invention, there being no allowable generic or

linking claim. Election was made without traverse in the reply filed on 21 February

2008.

Status of Application, Amendments, And/Or Claims

The preliminary amendments of 20 December 2004, 23 February 2006, and 21

February 2008 have been entered in full. Claims 1-35 are canceled, claims 37-50 are

withdrawn from consideration as discussed above, and claim 36 is under examination.

Specification

The title of the invention is not descriptive. A new title is required that is clearly

indicative of the invention to which the claims are directed.

The following title is suggested: METHOD OF PREPARING AN OSTEOGENIC

PROTEIN FRACTION.

35 U.S.C. § 103

Art Unit: 1646

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over either of Scott et al. (1994, The Anatomical Record 238:23-30) or Yoshimura et al. (1993, Biol. Pharm. Bull. 16:444-447) in view of Kuberasampath et al. (U.S. Patent 4,968,590; issued 06 November 1990).

At p. 24, 3<sup>rd</sup> through 5<sup>th</sup> paragraphs of left column, Scott et al. teach a method of preparing an osteogenic protein fraction comprising extracting demineralized bone matrix with a solution of a guanidium salt (Gu-HCI), removing high molecular weight proteins exceeding 300 kDa by ultrafiltration (using Millicon Pellicon system which first excludes proteins over 100 kDa [including proteins over 300 kDa]), subjecting the lower molecular weight fraction to heparin affinity chromatography, and exchanging the purified osteogenic protein fraction into a solvent appropriate for human medical use (deionized H<sub>2</sub>O).

Similarly, Yoshimura et al. teach a method of preparing an osteogenic protein fraction comprising extracting demineralized bone matrix with a solution of a guanidium salt (Gnd.HCl), removing high molecular weight proteins exceeding 300 kDa by ultrafiltration (using Minitan ultrafiltration system which excludes proteins over 100 kDa [including proteins over 300 kDa]), subjecting the lower molecular weight fraction to heparin affinity chromatography, and exchanging the purified osteogenic protein fraction

into a solvent appropriate for human medical use (telopeptide-free type I collagen using alcohol precipitation). See p. 444-445, Materials and Methods section.

Neither Scott et al. nor Yoshimura et al. teach an additional purification step of hydroxyapatite chromatography. However, such was well known in the art at the time of the invention.

For example, Kuberasampath et al. teach the additional step of hydroxyapatite chromatography after heparin affinity chromatography. See col. 6-7.

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to add the hydroxyapatite chromatography step of Kuberasampath et al. after the purification steps of either of Scott et al. or Yoshimura et al. with a reasonable expectation of success, as such was the result of combining prior art elements according to known methods to yield predictable results.

Thus, the invention as a whole was *prima facie* obvious over the combined teachings of the prior art.

## Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth C. Kemmerer, Ph.D. whose telephone number is (571) 272-0874. The examiner can normally be reached on Monday through Friday, 9:00 a.m. to 5:30 p.m.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, Ph.D. can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ECK

/Elizabeth C. Kemmerer/ Primary Examiner, Art Unit 1646